K113725

510(K) SUMMARY

Date: September 10, 2012

SEP 13 2012

1) Applicant Information

510(k) Owner: O. N. Diagnostics, LLC
2150 Shattuck Ave. Suite 610
Berkeley, CA 94704

Contact Person: David Kopperdahl
Director, Research and Development
O. N. Diagnostics, LLC
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Phone 510-204-0688
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Establishment Reg. No.: Registration to occur following FDA clearance.

2) Device Identification

Trade Name: VirtuOst
Common Name: QCT Bone Densitometry
Classification Name: Bone Densitometer
Regulation Number: 21 CFR 892.1170
Device Classification: Class II

3) Identification of Predicate Devices

K983028: Hologic QDR X-Ray Bone Densitometers with an added feature of Estimation of Fracture Risk from BMD

K894854: QCT Bone Mineral Density Analysis Software

K072664: GE Lunar Femur Strength Software Option

K992246: Image Analysis QCT Bone Mineral Analysis (BMA) Software

4) Device Description

VirtuOst is a stand-alone software package that analyzes data in computed tomography (CT) scans to measure bone mineral density (BMD), bone strength, and a load-to-strength ratio at the proximal femur and vertebral body. BMD is measured from both a

2D projection (in g/cm^2) and a volumetric scan reconstruction (in mg/cm^3) of the CT scan. VirtuOst measurements can be used by a physician to identify osteoporosis, assess fracture risk, and monitor therapy.

5) Intended Use

VirtuOst uses data from computed tomography scans to estimate bone mineral density, bone strength, and a load-to-strength ratio. This information can be used by a physician to assess fracture risk, identify osteoporosis, and monitor therapy.

6) Substantial Equivalence

Summary of Technology Characteristics and Comparison with Predicate Devices

VirtuOst provides measurements of areal BMD, in g/cm^2 and fracture risk classifications that are substantially equivalent to those obtained using predicate device **K983028**, and measurements of volumetric BMD, in mg/cm^3, that are substantially equivalent to those obtained from predicate device **K894854**. VirtuOst also provides measurements of bone strength and a load-to-strength ratio, substantially equivalent to the structural properties of the whole bone that are provided by predicate device **K072664**. VirtuOst has the same technological characteristics as the predicate devices and is comparable in safety and effectiveness, and has the same intended uses.

Summary of Performance Data

Clinical Performance Tests: Clinical studies demonstrated the substantial equivalence for measurements of bone mineral density between VirtuOst and predicate densitometers which used either DXA or computed tomography scans as input. Clinical repositioning studies demonstrated that the precision of outcomes from VirtuOst and predicate devices are equivalent. Results from a number of clinical fracture surveillance studies demonstrated that fracture risk assessment by VirtuOst estimates of whole-bone strength and the load-to-strength ratio, are at least as good as fracture risk assessment by DXA and QCT estimates of BMD.

Non-clinical Performance Tests: Strength of the proximal femur and vertebral body estimated using VirtuOst are statistically equivalent to strength as measured by direct mechanical testing in cadaver experiments.

6) Conclusion

A comparison of fundamental technological characteristics as well as of data obtained from observational clinical studies demonstrates that the performance, safety and effectiveness of VirtuOst are substantially equivalent to those of the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Mr. David Kopperdahl
Director, Research and Development
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Re: K113725
Trade/Device Name: VirtuOst
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, KGI
Dated: August 3, 2012
Received: August 8, 2012

Dear Mr. Kopperdahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number: K113725

Device Name: VirtuOst

Indications for Use:

VirtuOst uses data from computed tomography scans to estimate bone mineral density, bone strength, and a load-to-strength ratio. This information can be used by a physician to assess fracture risk, identify osteoporosis, and monitor therapy. For pediatric patients, VirtuOst provides these estimates without any classifications and should be used only when the benefit of obtaining these estimates outweighs the risk of radiation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR Part 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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